IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC., Plaintiff,	:	CIVIL ACTION
v.	:	No. 2:06-cv-2768
CEPHALON, INC., et al., Defendants.	:	

ORDER

AND NOW, this 3rd day of March, 2011, upon consideration of Defendant, Cephalon, Inc.'s, "Motion to Compel Production of Discovery from Plaintiff Apotex, Inc. Regarding Deficiencies in Current Good Manufacturing Practices," (doc. no. 380), Plaintiff's response in opposition, and Defendant's reply, the Court finds as follows:

1) On July 1, 2010, we issued a detailed Order regarding the production of discovery related to the Food & Drug Administration's (hereinafter "FDA") investigation of Apotex's Current Good Manufacturing Practices (hereinafter "CGMP") violations. This Order was issued in the patent portion of this case and in response to Cephalon's motion to compel documents related to a CGMP violation issued by the FDA. In response to this motion, Apotex was ordered to produce any and all documents falling within several categories specific to generic modafinil/ANDA No. 77-667 that related to the FDA investigation. This Order also placed Apotex under the continuing obligation to produce new materials related to the CGMP issues specific

to ANDA No. 77-667.

2) Cephalon has now filed a similar motion in the antitrust portion of this case. In addition to the specific information referenced in our July 1, 2010 Order, Cephalon again seeks a broad swath of discovery materials related to Apotex's manufacturing practices for all pharmaceutical products for a time period spanning more than a decade. While acknowledging that the Court has already determined that non-ANDA No. 77-667 information is not discoverable in the patent case, Cephalon asks us to find that it is discoverable in the antitrust case. Specifically, Cephalon posits that CGMP information for other pharmaceutical products is now discoverable on the issue of Apotex's ability to enter and remain in the market and Apotex's "but-for" damages. Cephalon's current request is denied for several reasons.

3) First, Cephalon's argument on Apotex's ability to enter and remain in the market in light of CGMP issues is in many ways the same argument the Court has already considered and ruled upon in our July 1, 2010 Order.

4) Second, Cephalon's argument that CGMP discovery is necessary to appropriately calculate damages is based on a litany of "what-ifs," hypotheticals, assumptions and speculation related to the past, present and future business of Apotex and the FDA. For instance, Cephalon asserts that the FDA "may" deny Apotex's petition for final approval on ANDA No. 77-667.

5) We acknowledge that a "but-for world" damages calculation is necessarily based on some speculation, and the Third Circuit has stated its skepticism of those types of models for that very reason. Rossi v. Standard Roofing Inc., 156 F.3d 452, 484-87

(3d Cir. 1998). In order for a "but-for" model to be an acceptable damages calculation it must be based on reasonable foundation, and Apotex will be required to meet that burden at trial. Id. at 487. To the extent that Apotex intends to use a "but-for world" damages calculation that implicates any CGMP information for non-modafinil products, Apotex will be precluded from introducing that information at trial if it was not disclosed during discovery.

6) Although Cephalon is permitted to defend its case in a manner of its own choosing, which may or may not include the need to compile a "but-for world" damages calculation, Cephalon's discovery requests are nonetheless constrained by the Federal Rules of Civil Procedure. The dispute between these two parties involves patent and antitrust issues based on generic modafinil/ANDA No. 77-667. At this juncture, Cephalon has not met its burden in demonstrating the discoverability of any and all non-ANDA No. 77-667 CGMP information. Even if Cephalon could meet that standard, the requests in their current form are overly broad and unduly burdensome. Cephalon has not addressed Apotex's assertion that discovery on all of its pharmaceutical products for the past eleven years which may have been linked to any CGMP issue is, in fact, unduly burdensome and overly broad.

7) In sum, Cephalon can certainly seek all of Apotex's discoverable material to which it is entitled under the Federal Rules of Civil Procedure, and this Court has already ordered Apotex to provide such material. There is a point, however, where discovery requests can be over burdensome. Even if we were to accept Cephalon's position on the "but-for world" damages calculation, such a calculation does not necessitate the

production of all CGMP information on all pharmaceutical products for the last eleven years.

WHEREFORE, it is hereby **ORDERED** that Defendant's motion is **DENIED**. **IT IS FURTHER ORDERED** that Cephalon may only conduct Rule 30(b)(6) depositions on topics 1-7 and 12 of its first notice of depositions in accordance with this Order and the Court's July 1, 2010 Order.

We further note that Apotex is under the continuing obligation pursuant to the Federal Rules of Civil Procedure and our July 1, 2010 Order to produce documents related to generic modafinil/ANDA No. 77-667 CGMP issues. The Court understands that there has been a coordinated discovery effort between the patent and antitrust cases, and consequently, all documents produced pursuant to our July 1, 2010 Order should have been provided to counsel in the antitrust case.

BY THE COURT:

/s/ Mitchell S. Goldberg

MITCHELL S. GOLDBERG, J.